

Internal Revenue Service

Department of the Treasury

Washington, DC 20224

Person to Contact: [REDACTED]

Telephone Number: [REDACTED]

Refer Reply to:

CP:E:EO:T:5

Date: NOV - 1 1995

Employer Identification Number: [REDACTED]

Key District: Southeast (Baltimore, MD)

Dear Applicant:

We have considered your application for recognition of exemption from federal income tax under section 501(a) of the Internal Revenue Code as an organization described in section 501(c)(3). Based on the information submitted, we have concluded that you do not qualify for exemption under that section. The basis for our conclusion is set forth below.

According to your Form 1023 Application and correspondence, you were organized on [REDACTED] as a [REDACTED] nonprofit corporation. Your sole member, [REDACTED], appoints your directors. You currently conduct or plan to conduct five different activities, some of which involve the sale of goods or services for a fee. Your fees are based on cost, including overhead. You will conduct your activities through independent contractors and employees, except where indicated otherwise below. The five activities are as follows:

1. You will direct and conduct basic research on organ and tissue transplantation, on behalf of [REDACTED] and other organizations in the field. The activity will be funded with grants and royalties and will be carried out mainly by grants to universities. The results of such research will generally be made available to the public through submission for publication in medical journals.

2. You will coordinate clinical studies for other organizations for a fee. Such studies will be primarily related to the pre-market approval process for transplantation required by the FDA.

3. You currently provide consulting services for a fee to organizations seeking to comply with FDA and other governmental guidelines regarding allograft tissue (body tissue from corpses) for transplantation. You subcontract attorneys, consultants, and other staff. [REDACTED] has expertise regarding such guidelines.

4. You will provide management and consulting services to transplant-related organizations.

5. You will develop tissue banking technology to improve the quality and safety of allograft tissue. The technology will then be made available for license for a fee to nonprofit tissue banks. You currently hold a patent and a license and have two patent applications pending.

Your current source of support is fees for consulting services. You anticipate in future receiving grants as the greater part of your support, substantial royalties, and nominal income from gift shop sales of T-shirts, caps, mugs, etc. with the [REDACTED] logo that promote organ and tissue donation.

Section 501(c)(3) of the Internal Revenue Code exempts from federal income tax organizations organized and operated exclusively for charitable, educational, scientific, or certain other purposes, no part of the net earnings of which inures to the benefit of any private shareholder or individual.

Section 1.501(c)(3)-1(c)(1) of the Income Tax Regulations provides that an organization "operates exclusively" for exempt purposes only if it engages primarily in activities that accomplish such purposes. It does not operate exclusively for exempt purposes if more than an insubstantial part of its activities does not further such purposes.

Section 1.501(c)(3)-1(d)(1)(ii) of the regulations provides that an organization is not operated exclusively for exempt purposes unless it serves a public rather than a private interest. Thus, an organization must establish that it is not operated for the benefit of private interests, such as designated individuals, the creator or his family, shareholders of the organization, or persons controlled by such private interests.

Section 1.501(c)(3)-1(d)(5)(i) of the regulations provides that the term "scientific" includes the carrying on of scientific research in the public interest. For research to be "scientific" it must be carried on in furtherance of a "scientific" purpose. The determination as to whether research is "scientific" does not depend on whether such research is classified as "fundamental" or "basic" as contrasted with "applied" or "practical."

Section 1.501(c)(3)-1(d)(5)(ii) of the regulations provides that scientific research does not include activities of a type ordinarily carried on as an incident to commercial or industrial

operations, as, for example, the ordinary testing or inspection of materials or products or the designing or construction of equipment, buildings, etc.

Section 1.501(c)(3)-1(d)(5)(v) of the regulations provides that the fact that any organization carries on research which is not in furtherance of an exempt purpose will not preclude such organization from meeting the requirements of section 501(c)(3) of the Code so long as the organization is not operated for the primary purpose of carrying on such research.

Section 1.501(c)(3)-1(e)(1) of the regulations provides that an organization may meet the requirements of section 501(c)(3) of the Code although it operates a trade or business as a substantial part of its activities, if the operation of such trade or business is in furtherance of the organization's exempt purpose or purposes and if the organization is not organized or operated for the primary purpose of carrying on an unrelated trade or business, as defined in section 513. In determining the existence or nonexistence of such primary purpose, all the circumstances must be considered, including the size and extent of the trade or business and the size and extent of the activities which are in furtherance of one or more exempt purposes.

Rev. Rul. 68-373, 1968-2 C.B. 206, held not exempt under section 501(c)(3) of the Code an organization primarily engaged in clinically testing drugs for commercial pharmaceutical companies to comply with FDA requirements prior to marketing. The Service reasoned that the testing was incident to commercial operations and not scientific research and principally benefitted the manufacturer. The Service also reasoned that the activity did not constitute exempt "testing for public safety" since a drug is not a consumer product until approved by the FDA.

Rev. Rul. 72-369, 1972-2 C.B. 245, held not exempt under section 501(c)(3) of the Code a nonprofit organization formed to provide managerial and consulting services at cost to unrelated 501(c)(3) organizations. The organization's receipts were from services rendered and disbursements were for operating expenses. The Service reasoned that providing managerial and consulting services on a regular basis for a fee is trade or business ordinarily carried on for profit. The fact that the services were provided at cost and solely for exempt organizations was not sufficient to characterize this activity as charitable under section 501(c)(3). This case was distinguished from Rev. Rul. 71-529, 1971-2 C.B. 234, where an organization controlled by a group of exempt organizations provided investment management

services for a charge substantially less than cost, solely to that group.

Some of your activity appears to further charitable or scientific purposes; namely, activities #1 and #5 above. However, it appears that most of your planned activity, and all of your current activity, is trade or business not in furtherance of exempt purposes. Activity #2 above is similar to the non-exempt activity described in Rev. Rul. 68-373, and activities #3 and #4 above are similar to the non-exempt activity described in Rev. Rul. 72-369. Under the circumstances, we find that you will be operated for the primary purpose of carrying on business unrelated to exempt purposes. We also find that these activities, which are substantial, will not further any exempt purposes. Therefore, you are not operated exclusively for exempt purposes.

Accordingly, you do not qualify for exemption as an organization described in section 501(c)(3) of the Code and you must file federal income tax returns.

Contributions to you are not deductible under section 170 of the Code.

You have the right to protest this ruling if you believe it is incorrect. To protest, you should submit a statement of your views, with a full explanation of your reasoning. This statement, signed by one of your officers, must be submitted within 30 days from the date of this letter. You also have a right to a conference in this office after your statement is submitted. You must request the conference, if you want one, when you file your protest statement. If you are to be represented by someone who is not one of your officers, that person will need to file a proper power of attorney and otherwise qualify under our Conference and Practices Requirements.

If you do not protest this ruling in a timely manner, it will be considered by the Internal Revenue Service as a failure to exhaust available administrative remedies. Section 7428(b)(2) of the Code provides, in part, that a declaratory judgement or decree under this section shall not be issued in any proceeding unless the Tax Court, the United States Court of Federal Claims, or the District Court of the United States for the District of Columbia determines that the organization involved has exhausted administrative remedies available to it within the Internal Revenue Service.

[REDACTED]

If we do not hear from you within 30 days, this ruling will become final and copies will be forwarded to your key district office. Thereafter, any questions about your federal income tax status should be addressed to that office. The appropriate State Officials will be notified of this action in accordance with Code section 6104(c).

When sending additional letters to us with respect to this case, you will expedite their receipt by using the following address:

Internal Revenue Service  
Attn: CP:E:EO:T:5 WT, Room 6539  
1111 Constitution Ave, N.W.  
Washington, D.C. 20224

If you have any questions, please contact the person whose name and telephone number are shown in the heading of this letter.

Sincerely,

(signed) [REDACTED]

[REDACTED]  
Chief, Exempt Organizations  
Technical Branch 5

[REDACTED]  
cc:

cc: [REDACTED] State officials

cc: DD, Southeast  
Attn: EO Group

[REDACTED]:pc/CP:E:EO:T:5/10-31-95

initiator reviewer  
CP E E O T S CP E E O T S  
[REDACTED] Curry  
10/31/95 5/Ch  
10/31/95